

REMARKS

The claims remaining in the application are claims 1-16, 18-24 and 27-30.

All of the claims have been rejected under the second paragraph of 35 USC § 112 as being indefinite. This rejection is respectfully traversed.

Each specific ground of rejection will be discussed in turn with the corrective amendment and, where necessary, indication of support in the original disclosure. The recitation "where appropriate" no longer appears in any of the claims. The recitation "conventional" no longer appears in any of the claims.

Claims 10-12 are now dependent on claim 2, which lists components a), b) and c). Thus, the references in claims 10-12 are now understandable. The recitation objected to in claim 13 was redundant. For a further explanation, see page 16 of the specification.

The examiner's objection to claim 14 is not completely understood. It is considered that one of ordinary skill in the relevant art (chemistry) understands that a multiply charged cation is a cation having a positive charge of more than 1. For example, Ca^{++} and Al^{+++} . That is opposed to singly charged cations, such as Na^+ and K^+ .

Claims 23-26 have been amended to statutory composition claims. They are now dependent on claim 20 and recite species or subgenuses of the genus of claim 20.

The word "shell" no longer appears in any of the claims. It was simply intended as a synonym for "capsule."

Claim 14 has antecedent basis in claim 13, from which it is now dependent.

It is believed that the amendments to claims 9 and 14-16 and new claims 27-29 contain the type of Markush expression the examiner is familiar with.

All new numerical ranges now recited in the claims are supported in the original specification at page 29, lines 6-11, page 10, lines 20-25, and page 21, lines 10-11. The Markush group recited in claim 1 is supported by original claim 17, and at page 28, lines 9-13, of the specification.

Any points of indefiniteness remaining in the claims reflect inadvertent errors, since applicants have made a good faith attempt to correct all of them. Applicants are amenable to a telephone conference initiated by the examiner to the undersigned if the examiner believes that such a conference would be of value in placing the claims in condition for allowance.

Claims 1-8, 10-13, 15, 16 and 18-20 have been rejected under 35 USC § 102(b) as being anticipated by Harreus et al., US 3,984,494 (Harreus). This rejection is respectfully traversed.

The rejection is *per se* erroneous. Harreus discloses only what is known in the art as "hard" capsules. The discussion of relative hardness and softness at col. 2, lines 17-24, relates only to degrees of hardness or softness within the context of "hard" capsules. The term that Harreus uses, "self-supporting," in this art is synonymous with "hard." The German equivalent of Harreus was cited at page 3, lines 35-39, of the original specification. The distinctions between hard and soft capsules which make

them, in effect, quite different fields of art, are discussed from page 3, line 41, to page 4, line 27, of the specification.

As further authority for the foregoing statements, applicants cite *Ullmann's Encyclopedia of Industrial Chemistry*, Vol. A19, p. 250, "**Capsules and Cachets**," copy attached hereto.

For the foregoing reasons, the reference can not constitute an anticipation under 35 USC § 102, the requirements for which are set forth in MPEP § 2131 and the cases cited therein.

Claims 1-8, 10-13, 15, 16 and 18-20 have been rejected under 35 USC § 103(a) as being unpatentable over Harreus. This rejection is respectfully traversed.

The rejection is based on the obviousness of an asserted optimization. However, one can not have "optimization" where the claims relate to a completely different subject matter and are outside the range taught by the reference. *In re Sebek*, 465 F.2d 904, 907, 175 USPQ 93, 95 (CCPA 1972). See also *In re Antonie*, 559 F.2d 689, 195 USPQ 6, 8, 9 (CCPA 1977); MPEP § 2144.05(IIB) is also relevant.

The authorities cited above should make it quite clear that the present claims drawn to "hard" capsules can not represent a mere optimization of the disclosure of "soft" capsules by Harreus.

Claims 14, 17, 21 and 23 have been rejected under 35 USC § 103 as being unpatentable over Harreus in view of Cade et al., WO 98/27151 (Cade). This rejection is respectfully traversed.

In the **Abstract**, Cade recites "hard and soft capsules." However, the entire enabling disclosure is related to hard capsules as they are known in the prior art. See particularly page 5, lines 6-16 and all of the working examples. Thus, the disclosure of Cade can not remedy any of the deficiencies of Harreus with respect to supporting a *prima facie* case of obviousness against any of the claims in this application. Even if Harreus really did disclose, in a meaningful way, soft capsules, the propriety of the combination of references would be questionable. *In re Clay*, 23 USPQ2d 1058, 1060 (Fed. Cir. 1992). *In re Wright*, 848 F.2d 1216, 6 USPQ2d 1959 (Fed. Cir. 1988).

Claim 9 has been rejected under 35 USC § 103 as being unpatentable over Harreus in view of Boeckh et al., US 5,972,508 (Boeckh). This rejection is respectfully traversed.

The major thrust of the Boeckh disclosure is the preparation of "microcapsules containing bleaching agents." Other cleaning agents may be included, but there is no disclosure of any kind relevant to the pharmaceutical capsules of Harreus. Thus, the impropriety of this combination of references is absolutely clear in view of the cases cited above.

In light of the foregoing amendments and remarks, applicants consider that all of the examiner's rejections have been obviated, and it is respectfully requested that this application be passed to issue.


A check to cover the two month extension fee of \$420.00 is attached.

Please charge any shortage in fees due in connection with the filing of this

paper, including Extension of Time fees to Deposit Account No. 11-0345. Please credit any excess fees to such deposit account.

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

Cancel claims 17, 25 and 26; amend claims 1-16 and 18-24; and add new claims 27-30 as follows:

1. (amended) A soft capsule comprising

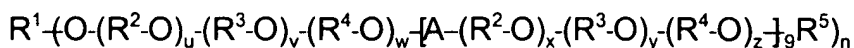
- (a) from 10 to 100% of polymers prepared by polymerization of vinyl esters in the presence of polyethers
- (b) [where appropriate] from 0 to 80% of structure-improving auxiliaries and
- (c) [where appropriate other conventional] from 0 to 30 % of other constituents selected from the group consisting of fillers, release agents, flow aids, stabilizers, water-soluble or water-insoluble dyes, flavorings and sweeteners.

2. (amended) A soft capsule as claimed in claim 1, wherein [the] said polymers (a) are [obtainable] produced by free-radical polymerization of

- a) at least one vinyl ester of C₁-C₂₄-carboxylic acids in the presence of
- b) polyether-containing compounds and
- c) [where appropriate] from 0 to 50% of one or more copolymerizable monomers and subsequent at least partial hydrolysis of the ester functions in the original monomers a).

3. (twice amended) A soft capsule as claimed in claim 1, wherein the polymers (a) are [obtainable] obtained by free-radical polymerization of

- a) at least one vinyl ester of C₁-C₂₄-carboxylic acids in the presence of
- b) polyether-containing compounds of the general formula I



in which the variables have, independently of one another, the following meaning:

R^1 hydrogen, C_1 - C_{24} -alkyl, R^6 -C(=O)-, R^6 -NH-C(=O)-, polyalcohol residue;

R^5 hydrogen, C_1 - C_{24} -alkyl, R^6 -C(=O)-, R^6 -NH-C(=O)-;

R^2 to R^4 $-(CH_2)_2-$, $-(CH_2)_3-$, $-(CH_2)_4-$, $-CH_2-CH(R^6)-$, $-CH_2-CHOR^7-CH_2-$;

R^6 C_1 - C_{24} -alkyl;

R^7 hydrogen, C_1 - C_{24} -alkyl, R^6 -C(=O)-, R^6 -NH-C(=O)-;

A $-C(=O)-O$, $-C(=O)-B-C(=O)-O$, $-C(=O)-NH-B-NH-C(=O)-O$;

B $-(CH_2)_t-$, arylene, optionally substituted;

n 1 to 1000;

s 0 to 1000;

t 1 to 12;

u 1 to 5000;

v 0 to 5000;

w 0 to 5000;

x 0 to 5000;

y 0 to 5000;

z 0 to 5000;

and

c) [where appropriate] from 0 to 50% of one or more other copolymerizable monomers

and subsequent at least partial hydrolysis of the ester functions in the original monomers a).

4. (twice amended) A soft capsule as claimed in claim 1, wherein the polymers (a) are [obtainable] obtained by free-radical polymerization of

- a) at least one vinyl ester of C_1 - C_{24} -carboxylic acids in the presence of
- b) polyether-containing compounds of the general formula I with a number average molecular weight of from 300 to 100000, in which the variables have, independently of one another, the following meaning:

R^1 hydrogen, C_1 - C_{12} -alkyl, R^6 -C(=O)-, R^6 -NH-C(=O)-, polyalcohol residue;

R^5 hydrogen, C_1 - C_{12} -alkyl, R^6 -C(=O)-, R^6 -NH-C(=O)-;

R^2 to R^4 $-(CH_2)_2-$, $-(CH_2)_3-$, $-(CH_2)_4-$, $-CH_2-CH(R^6)-$, $-CH_2-CHOR^7-CH_2-$;

R^6 C_1 - C_{12} -alkyl;

R^7 hydrogen, C_1 - C_{12} -alkyl, R^6 -C(=O)-, R^6 -NH-C(=O)-;

n 1 to 8;

s 0;

u 2 to 2000;

v 0 to 2000;

w 0 to 2000;

and

- c) [where appropriate] one or more other copolymerizable monomers,

and subsequent at least partial hydrolysis of the ester functions in the original

monomers a).

5. (twice amended) A soft capsule as claimed in claim 1, wherein the polymers (a) are [obtainable] obtained by free-radical polymerization of

- a) at least one vinyl ester of C_1 - C_{24} -carboxylic acids in the presence of
- b) polyether-containing compounds of the general formula I with a number average molecular weight of from 500 to 50000, in which the variables have, independently of one another, the following meaning:

R^1 hydrogen, C_1 - C_6 -alkyl, R^6 -C(=O)-, R^6 -NH-C(=O)-;

R^5 hydrogen, C_1 - C_6 -alkyl, R^6 -C(=O)-, R^6 -NH-C(=O)-;

R^2 to R^4 $-(CH_2)_2-$, $-(CH_2)_3-$, $-(CH_2)_4-$, $-CH_2-CH(R^6)-$, $-CH_2-CHOR^7-CH_2-$;

R^6 C_1 - C_6 -alkyl;

R^7 hydrogen, C_1 - C_6 -alkyl, R^6 -C(=O)-, R^6 -NH-C(=O)-;

n 1;

s 0;

u 5 to 1000;

v 0 to 1000;

w 0 to 1000;

and

- c) [where appropriate] one or more other copolymerizable monomers, and subsequent at least partial hydrolysis of the ester functions in the original monomers a).

6. (twice amended) A soft capsule as claimed in claim 1, wherein the polymers (a) are

[obtainable] obtained by free-radical polymerization of

a) at least one vinyl ester of C₁-C₂₄-carboxylic acids in the presence of

b) polyether-containing compounds and

c) [where appropriate] one or more other copolymerizable monomers,

and subsequent at least partial hydrolysis of the ester functions in the original

monomers a), wherein the polyether-containing compounds b) have been prepared by

polymerization of ethylenically unsaturated alkylene oxide-containing monomers [and,

where appropriate,] , alone or together with other copolymerizable monomers.

7. (twice amended) A soft capsule as claimed in claim 6, wherein the

polyether-containing compounds b) have been prepared by polymerization of

polyalkylene oxide vinyl ethers and, [where appropriate,] alone or together with

other copolymerizable monomers.

8. (twice amended) A soft capsule as claimed in claim 6, wherein the

polyether-containing compounds b) have been prepared by polymerization of

polyalkylene oxide (meth)acrylates [and, where appropriate], alone or together

with other copolymerizable monomers.

9. (twice amended) A soft capsule as claimed in claim [1] 2, wherein [the] said other

copolymerizable [monomer] monomers c) [is] are selected from the group

consisting of:

acrylic acid, methacrylic acid, maleic acid, fumaric acid, crotonic acid, maleic

anhydride and its monoesters, methyl acrylate, methyl methacrylate, ethyl acrylate, ethyl methacrylate, n-butyl acrylate, n-butyl methacrylate, t-butyl acrylate, t-butyl methacrylate, isobutyl acrylate, isobutyl methacrylate, 2-ethylhexyl acrylate, stearyl acrylate, stearyl methacrylate, N-t-butylacrylamide, N-octylacrylamide, 2-hydroxyethyl acrylate, hydroxypropyl acrylates, 2-hydroxyethyl methacrylate, hydroxypropyl methacrylates, alkylene glycol (meth)acrylates, styrene, unsaturated sulfonic acids [such as, for example, acrylamidopropanesulfonic acid, vinylpyrrolidone, vinylcaprolactam, vinyl ethers (for example: methyl, ethyl, butyl or dodecyl vinyl ether), vinylformamide, vinylmethylacetamide, vinylamine, 1-vinylimidazole, 1-vinyl-2-methylimidazole, N,N-dimethylaminomethyl methacrylate and N-[3-(dimethylamino)propyl]methacrylamide; 3-methyl-1-vinylimidazolium chloride, 3-methyl-1-vinylimidazolium methyl sulfate, N,N-dimethylaminoethyl methacrylate, N-[3-(dimethylamino)-propyl]methacrylamide quaternized with methyl chloride, methyl sulfate or diethyl sulfate].

10. (twice amended) A soft capsule as claimed in claim [1] 2, wherein the [ratios of amounts of a), b) and c) are

- a) 10 to 98% by weight
- b) 2 to 90% by weight
- c) 0 to 50% by weight.

11. (twice amended) A soft capsule as claimed in claim [1] 2, wherein the [ratios of]

amounts of a), b) and c) are

- a) 50 to 97% by weight
- b) 3 to 50% by weight
- c) 0 to 20% by weight.

12. (twice amended) A soft capsule as claimed in claim [1] 2, wherein the [ratios of]

amounts of a), b) and c) are

- a) 65 to 97% by weight
- b) 3 to 35% by weight
- c) 0 to 20% by weight.

13. (twice amended) A soft capsule as claimed in claim 1, wherein the resulting polymers are subsequently crosslinked [by a polymer-analogous reaction].

14. (twice amended) A soft capsule as claimed in claim [1] 13, wherein the resulting polymers are subsequently crosslinked by reaction with one or more compounds selected from the group consisting of dialdehydes, diketones, dicarboxylic acids, boric acid, boric acid salts, and salts of multiply charged cations [are employed for the subsequent crosslinking].

15. (twice amended) A soft capsule as claimed in claim 1, wherein the structure-improving auxiliaries (b) employed are compounds from the following classes:

- a) polymers with a molecular weight of more than 50000
- b) substances leading to crosslinking of the polymer chains of the polymers,

- c) and, [where appropriate,] optionally, substances which lead to crosslinking of the polymer chains of the structure-improving auxiliaries.

16. (twice amended) A soft capsule as claimed in claim 1, wherein the

structure-improving auxiliaries employed are polymers selected from the group consisting of the following classes of substances:

polyamino acids [such as gelatin, zein, soybean protein and derivatives thereof], polysaccharides [such as starch, degraded starch, maltodextrins, carboxymethylstarch, cellulose, hydroxypropylmethylcellulose, hydroxypropylcellulose, hydroxyethylcellulose, methylcellulose, carboxymethylcellulose, ethylcellulose, cellulose acetate, cellulose acetate phthalate, hydroxypropylcellulose acetate phthalate, hydroxypropylcellulose acetate succinate, hemicellulose, galactomannans, pectins, alginates, carrageenans, xanthan, gellan, dextran, curdlan, pullulan, gum arabic, chitin, and derivatives thereof,] and synthetic polymers [such as polyacrylic acid, polymethacrylic acid, copolymers of acrylic esters and methacrylic esters, polyvinyl alcohols, polyvinyl acetate, polyethylene glycols, polyoxyethylene/polyoxypropylene block copolymers, polyvinylpyrrolidones and derivatives thereof].

18. (amended) A soft capsule as claimed in claim 1, [wherein the shell] which consists of from 10 to 100% by weight of polymers of vinyl esters on polyether, [where appropriate] from 0 to 80% of structure-improving auxiliaries and, [where

- appropriate,] from 0 to 30% of said other [conventional] constituents.
19. (amended) A soft capsule as claimed in claim 1, [obtainable by processes such as] obtained by a process selected from the group consisting of the rotary die process, Accogel process, Norton process, drop or blow process or the Colton-Upjohn process.
20. (twice amended) A soft capsule as claimed in claim 1, which comprises one or more active pharmaceutical ingredients, vitamins, carotenoids, minerals, trace elements, food supplements, cosmetic active ingredients, crop protection agents, bath additives, perfume, flavoring, [cleaner or detergent] cleaners or detergents.
21. (twice amended) A soft capsule as claimed in claim 1, wherein the [shell] capsule comprises from 20 to 80% of a polymer resistant to gastric fluid.
22. (twice amended) A soft capsule as claimed in claim 1, wherein resistance to gastric fluid is achieved by applying after production a coating resistant to gastric fluid by [conventional] pharmaceutical coating processes.
23. (twice amended) [The use of the] The soft [capsules] capsule as claimed in claim [1 for] 20 which comprises one or more pharmaceutical [applications] ingredients.
24. (twice amended) [The use of the] The soft [capsules] capsule as claimed in claim [1 for] 20 which comprises one or more cosmetic [applications, applications in crop protection, for] active ingredients, crop protection agents, cleaners or food supplements.
27. (new) A soft capsule as claimed in claim 16, wherein said polyamino acids are

selected from the group consisting of gelatin, zein, soybean protein and derivatives thereof.

28. (new) A soft capsule as claimed in claim 16, wherein said polysaccharides are selected from the group consisting of starch, degraded starch, maltodextrins, carboxymethylstarch, cellulose, hydroxypropylmethylcellulose, hydroxypropylcellulose, hydroxyethylcellulose, methylcellulose, carboxymethylcellulose, ethylcellulose, cellulose acetate, cellulose acetate phthalate, hydroxypropylcellulose acetate phthalate, hydroxypropylcellulose acetate succinate, hemicellulose, galactomannans, pectins, alginates, carrageenans, xanthan, gellan, dextran, curdlan, pullulan, gum arabic, chitin, and derivatives thereof.
29. (new) A soft capsule as claimed in claim 16, where said synthetic polymers are selected from the group consisting of polyacrylic acid, polymethacrylic acid, copolymers of acrylic esters and methacrylic esters, polyvinyl alcohols, polyvinyl acetate, polyethylene glycols, polyoxyethylene/polyoxypropylene block copolymers, polyvinylpyrrolidones and derivatives thereof.
30. (new) A soft capsule as claimed in claim 1, wherein the amounts of (a), (b) and (c) are:
- (a) 20 to 98% by weight;
 - (b) 1 to 50% by weight; and
 - (c) 0.1 to 30% by weight.